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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/752,438

01/05/2004

Wolfgang Fitz

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3735

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BOSTON, MA 02110-1618

EXAMINER

STEWART, JASON-DENNIS NEILKEN

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

02/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No. 10/752,438	Applicant(s) FITZ ET AL.	
	Examiner JASON-DENNIS STEWART	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a Final Office action in response to communications received on 12/18/2008. Claims 1, 27, 28, and 31-39 have been amended. Therefore, Claims 1 and 3-46 are pending and addressed below.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2008 has been entered.

Response to Amendment

The amendments to the claims are sufficient to overcome the U.S.C. 112, 2nd paragraph rejections of the last Office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 12-14, 16-18, 26, 28-31, 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckhoff 5,681,354.

4. Eckhoff discloses an implant for implantation on the femoral condyle that has a joint facing surface and a bone facing surface. The implant opposes both a portion of the condyle and the trochlea (Fig. 1) and also has a surface cut and a constant thickness over the implant (Fig. 2). Eckhoff further discloses a plurality of symmetrical pins 11 for attachment to the bone surface. The shape of the implant substantially matches the articulating surfaces of the distal femur on the bone facing side and proximal tibia or proximal tibial implant of the joint facing side (Fig. 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-5, 8, 9, 11, 19-25, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff 5,681,354 in view of Fell 2003/0055501.

Eckhoff discloses the invention as claimed and as discussed above. However, although implied, Eckhoff does not disclose a specific thickness of the implant.

Fell discloses a metal implant (paragraph 14) that comprises biologically active materials (paragraph 72) used to correct cartilage defects in the knee joint and discloses the implant will be the thickness of the defect and could also have varying thickness depending on cartilage wear (paragraphs 17, 54). The device is implanted via a 3cm-5cm incision. Fell also discloses the joint being restored to full extension and 120 degrees of flexion. Fell further discloses that the implant is selected from a library of implants as well (paragraph 25, 95).

It would have been obvious to one of ordinary skill in the art to use the thickness, coating, and incision of Fell with the device of Eckhoff in order to effectively replace worn articular cartilage, restore normal joint alignment, as taught by Fell (paragraph 25).

7. Claims 6, 7, 10, and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff 5,681,354 in view of Fell 2003/0060882.

Eckhoff discloses the invention as claimed and as discussed above. However, Eckhoff does not disclose an offset thickness.

Fell '882 discloses a metal knee prosthesis (paragraph 74) with biologically active surfaces and an offset defined by a ratio (paragraph 28, fig. 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Eckhoff with the offset of Fell '882 in order to restore normal joint alignment without requiring any bone resection as taught by Fell '882 (paragraph 17).

8. Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff 5,681,354 in view of Rolston 2004/016730.

Art Unit: 3738

Eckhoff discloses the invention as claimed and as discussed above. However, Eckhoff does not disclose a second implant component that covers a portion of the patellar surface. Rolston discloses a second component 58 that has a first surface that engages the femur mating surface of the patella and a second surface that engages the patella (fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Eckhoff with the patellar implant of Rolston in order to remedy a patella that is also diseased as taught by Rolston (paragraph 5).

Response to Arguments

9. Applicant's arguments filed 12/18/2008 have been fully considered but they are not persuasive.

10. Applicant argues that Eckhoff neither teaches nor suggests at least a portion of the bone-facing implant surface have a three-dimensional shape that substantially matches the shape of a least a portion of an uncut articular surface that the bone-facing surface abuts. Examiner respectfully disagrees. First, it should be noted that the limitation "having a 3-D shape that substantially matches the shape of a least a portion of the uncut articular surface" does not describe any particular structure that is patentable over the prior art. It is well known in the art and also makes intuitive sense to make orthopedic implants that have bone facing surfaces that match the surface that they abut in order to prevent implant failure and to allow the implant to act as closely as possible to the function of normal, healthy anatomy. Figure 1 of Eckhoff clearly

Art Unit: 3738

illustrates a prosthesis intended to mate with the distal end of the femur including trochlea and femoral condyles. The inner surface of this implant has at least flange portions that at least *substantially* match the articulating surface of the femoral condyles.

Conclusion

11. This is an RCE of applicant's earlier Application No. 10/752438. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number

Art Unit: 3738

is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738